CLAIMS

1. A process of preparing finasteride Form I, which process comprises dissolving finasteride in a solvent, replacing the solvent partially or substantially completely with a non-solvent and thereafter isolating finasteride Form I.

2. A process according to claim 1, wherein replacement of said solvent comprises distilling off said solvent followed by addition of said non-solvent.

3. A process of preparing finasteride Form I, which process comprises the steps of: (i) dissolving finasteride in a solvent to form a solution; (ii) distilling off the solvent from the solution obtained in step (i); (iii) adding a non-solvent to the product of step (ii); and (iv) isolating finasteride Form I.

4. A process according to any of claims 1 to 3, wherein said solvent is methanol or dichloromethane.

5. A process according to any of claims 1 to 4, wherein dissolution of said finasteride in said solvent is carried out at a temperature in the range of ambient to reflux.

6. A process according to any of claims 1 to 5, wherein a finasteride solution obtained further to addition of finasteride to said solvent is clarified using decolourising agents.

7. A process according to any of claims 1 to 6, wherein said non-solvent is water.

8. A process according to any of claims 1 to 6, wherein said non-solvent is an organic solvent in which the solubility of finasteride in not more than about 5%w/v.

9. A process according to claim 8, wherein said organic non-solvent is selected from the group consisting of hexane, heptane, octane, toluene, xylene, isobutyl acetate and isopropyl acetate.

10. A process according to any of claims 1 to 9, which further comprises distillation following addition of said non-solvent.

11. A process according to any of claims 1 to 10, which further comprises stirring a precipitated product obtained further to addition of said non-solvent so as to obtain finasteride Form I.

12. A process of preparing finasteride Form I, which process comprises dissolving finasteride in a solvent, replacing the solvent partially or substantially completely with a non-solvent, stirring a precipitated product obtained further to addition of the non-solvent and thereafter isolating finasteride Form I.

13. Finasteride Form I prepared by a process according to any of claims 1 to 12.

14. Finasteride Form I having a purity of at least about 99.6%w/w.

15. Finasteride Form I having a purity of at least about 99.7%w/w.

16. Finasteride Form I having a purity of at least about 99.8%w/w.

17. A pharmaceutical composition comprising a therapeutically effective amount of finasteride Form I according to any of claims 13 to 16, together with one or more pharmaceutically acceptable carriers, diluents or excipients therefor.

18. Finasteride Form I according to any of claims 13 to 16, for use in therapy.

19. A method of inhibiting 5-alpha reductase in a patient in need thereof comprising administering to said patient an effective inhibitory amount of finasteride Form I according to any of claims 13 to 16.

20. Finasteride Form I according to any of claims 13 to 16, for use in the manufacture of a medicament for inhibiting 5-alpha reductase.